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A RANDOMISED STUDY TO COMPARE THE PELVICTONER DEVICE AGAINST STANDARD PELVIC FLOOR EXERCISES IN THE TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

Hypothesis / aims of study

The ICIQ recommend that supervised pelvic floor muscle training (PFMT) be offered as first line treatment for women with stress or mixed urinary incontinence. Adjunctive measures, such as vaginal cones and electrical stimulation are not advocated as they have yet to produce sufficient evidence of efficacy [1]. PFMT typically involves helping the woman confidently identify when she is achieving a satisfactory pelvic floor contraction, and a regime of unresisted contractions; the importance of professional supervision to achieve successful results with PFMT is recognised.

We hypothesised that using the PelvicToner Device (PTD) to introduce resistance intravaginally against the pelvic floor contraction may facilitate PFMT, improve muscle strength and aid the woman gain confidence in successfully complying with PFMT. Accordingly, the aim of this study was to investigate the efficacy, acceptability and patient satisfaction of the PTD as a viable adjunct to PFMT when compared against PFMT alone

Study design, materials and methods

This was a single centre, parallel group, randomised controlled study. Women over 18 years with symptoms of pure stress or stress-predominant mixed urinary incontinence (a minimum of three stress urinary leaks/ week based on bladder diary), who had not undergone surgery for incontinence, were recruited between February and December 2008. Study interventions took place within North Bristol NHS Trust secondary care facility.

Subjects were randomly assigned to one of two interventions; a standard treatment (ST) group (i.e. unresisted PFMT alone) or the PelvicToner group (i.e. PFMT employing the PTD). Subjects in both groups were individually informed of the anatomy and function of the pelvic floor muscles and how to correctly contract the muscles during a one hour visit with a health care professional. Subjects in the PTD group were given a PTD together with written and verbal instruction on its use. Following instruction, correct pelvic floor muscle contraction was confirmed by the use of a perineometer.

All subjects were instructed to carry out a standardised PFMT regime consisting of five 'quick' and five 'slow' (sustained) pelvic floor contractions, in the supine position twice daily over 16 weeks. Subjects in the PTD group were instructed to use the PTD concurrently whilst executing this regime. After two weeks all subjects were followed up by telephone in order to answer queries and reinforce technique, further review took place during visits at eight and sixteen weeks of treatment.

The primary efficacy endpoint for this study was the comparison of subject-reported improvement between treatment groups. Improvement was defined as a positive change by two or more levels in subject response to question 11a/b of the ICIQ-FLUTS questionnaire when administered at screening and on completion of the treatment period.

Primary Outcome Measure: Change in subject response to question 11a / b of ICIQ-FLUTS

11a) Does urine leak when you are physically active, exert yourself, cough or sneeze?

Response: Never, occasionally, sometimes, most of the time, all of the time

Subject demonstrates an improvement in symptoms reflected by a change in response to question 11a at screening from 'all of the time' to 'sometimes' at treatment completion

11b) How much does this bother you?

Response: Bother score 0 – 10 ('0' - 'not at all', '10' - 'a great deal').

Improvement being denoted by a positive change in response e.g. from '10' to '8'

Secondary outcome measures included subjective reports of 'cure', defined as the response of 'never' to question 11a ICIQ-FLUTS following the treatment period. Other measures included; the ICIQ-UI Short Form and ICIQ-LUTSqol questionnaires, the Patient Satisfaction Question (PSQ), Global Perception of Improvement (GPI), and Estimated Percent Improved (EPI). Subjective opinions regarding satisfaction and acceptability were also sought throughout the treatment phase.

The randomisation sequence was generated independently of the investigator; and allocation concealment comprised of placing randomisation slips into opaque sequentially-numbered sealed envelopes. Due to the nature of intervention, blinding of both subject and health care provider administrating the intervention as to treatment group, was unfeasible

Results

42 subjects were randomised; the results given are an interim analysis based on data collected from 30 completed subjects, (n=15 per treatment arm).

Responses to question of 5a ICIQ-LUTSqol indicated a declining trend in the impact of stress urinary incontinence on physical activities over the treatment period for subjects in both groups.

Table 1. - ICIQ-LUTSqol question 5a

Time * Does your urinary problem affect your physical activities? (e;g; going for a walk, run, sport, gym, etc.)?

% Within Time

Randomised Group	Not at all	Slightly	Moderately	A lot

PelvicToner				
Week 0 - Baseline	6.7%	13.3%	13.3%	66.7%
Week 16 - End of treatment	14.3%	50.0%	14.3%	21.4%
Standard Treatment				
Week 0 - Baseline	6.7%	26.7%	26.6%	40.0%
Week 16 - End of treatment	26.7%	40.0%	26.6%	6.7%

This was also reflected in responses to questions 17a and 22 of the ICIQ-LUTSqol, whereby subjects reported a decrease in pad use and a reduction in bother scores when asked how much their urinary symptoms interfered with everyday life at screening and following the treatment period.

In analysing the primary outcome, 67% of subjects (n=10) in the PTD group reported symptom improvement following the treatment phase, compared with 60% subjects (n=9) in the ST group. There was no statistical significant difference between the groups at any time point for this outcome measure. No subjects in the PTD group (n=0), and 13.3% (n=2) subjects in the ST group reported 'cure'

Overall group compliance was good and no adverse events occurred. 100% subjects when questioned reported the PTD easy to use, with 73% subjects (n=11) giving the device a satisfaction rating of $\geq$ 7/10 ('0' = 'dissatisfied', '10' = 'very satisfied').

Common reported themes from study subjects were that the PTD helped to isolate and focus on contracting the correct muscles, motivating the person to continue exercising. One lady remarked that the PTD increased her confidence by providing '…something tangible to measure the squeeze'.

Interpretation of results

The PTD is not inferior to standard PFMT, contrasting with other adjuncts such as vaginal cones and electrical stimulation. Subjective feedback highlights the potential for individual benefits which may promote subsequent compliance and sustained efficacy.

Concluding message

The PTD is not inferior to standard treatment; it is a safe and well tolerated adjunct to PFMT, which increases patient choice.

References

1. Wilson, P., Hay-Smith, J., Wyman, J. et al.:Adult Conservative Management. In: Incontinence. Proceedings from the Fourth International Consultation on Incontinence. Plymouth UK: Health Publications Ltd, 2009 pp.1025-1121

Specify source of funding or grant	**This research study was funded by Solution Project Management Ltd - the company who manufacture and distribute the PelvicToner device. The study was undertaken completely independant of company input and funding considerations have not inflouenced the scientific integrity of the work carried out.**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Southmead Research Ethics Committee gave ethical approval for this study to take place within North Bristol NHS Trust**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**